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Attorney's Docket No.: 01948-061001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Terry Strom, et al.
Serial No. : 09/778,013
Filed : February 6, 2001
Title : METHODS OF EVALUATING TRANSPLANT REJECTION

Art Unit : 1645
Examiner : Unknown

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449, copies of which are enclosed.

This statement is being filed before the receipt of a first Office action on the merits.

Please apply any charges to Deposit Account No. 06-1050 referencing 01948-061001.

Respectfully submitted,

Date: April 25, 2002

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Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce
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Information Disclosure Statement by Applicant
(Use several sheets if necessary)

(37 CFR §1.98(b))

Attorney's Docket No.	Application No.
01948-061001	09/778,013
Applicant: Terry Strom, et al.	
Filing Date: February 6, 2001	Group Art Unit: 1645

U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,569,588	Oct. 29, 1996	Ashby et al			
	AB	5,213,961	May 25, 1993	Bunn et al			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AC	Cassol, et al. *Primer-mediated Enzymatic Amplification of Cytomegalovirus (CMV) DNA*. J. Clin. Invest. 83:1109-1115 (Apr. 1989).
	AD	Eisen, et al. *Cluster analysis and display of genome-wide expression patterns.* Proc. Natl. Acad. Sci. USA 95:14863-14868 (1998).
	AE	Meyer-Konig, et al. *Human Cytomegalovirus Immediate Early and Late Transcripts in Peripheral Blood Leukocytes: Diagnostic Value in Renal Transplant Recipients.* Journal of Infection Diseases 171:705-709 (1995).
	AF	Lipman, et al. *Hightened Intragraft CTL Gene Expression in Acutely Rejecting Renal Allografts.* Journal of Immunology 152:1520 (1994).
	AG	Perou, et al. *Molecular portraits of human breast tumors.* Nature 406:747-752 (2000).
	AH	Ross, et al. *Systematic variation in gene expression patterns in human cancer cell lines.* Nature Genetics 24:227-235 (2000).
	AI	Rush, et al. *Sequential protocol biopsies in renal transplant patients.* Transplantation 59(4):511-514 (1995).
	AJ	Rush, et al. *Histological findings in early routine biopsies of stable renal allograft recipients.* Transplantation 57(2):208-211 (1994).
	AK	Wright, et al. *The polymerase chain reaction: miracle or mirage? A critical review of its uses and limitations in diagnosis and research.* Journal of Pathology 162:99-117 (1990).
	AL	Abraham, et al. *Transfection of the human heme oxygenase gene into rabbit coronary microvessel endothelial cells: Protective effect against heme and hemoglobin toxicity.* Proc. Natl. Acad. Sci. USA 92:6798-6802 (July 1995).
	AM	Agarwal, et al. *Induction of heme oxygenase in toxic renal injury: A protective role in cisplatin nephrotoxicity in the rat.* Kidney International 48:1298-1307 (1995).
	AN	Agarwal, et al. *Gas-generating systems in acute renal allograft rejection in the rat.* Transplantation 61(1):93-98 (1996).
	AO	Agarwal, et al. *Renal response to tissue injury: Lessons from heme oxygenase-1 gene ablation and expression.* J. Am. Soc. Nephrol. 11:965-973 (2000).
	AP	Agodoa et al. *Assessment of structure and function in progressive renal disease.* Kidney International 52(Supp.63):S144-S150 (1997).
	AQ	Aizawa, et al. *Heme Oxygenase-1 is upregulated in the kidney of angiotensin II-Induced Hypertensive Rats.* Hypertension 35:800-806 (2000).

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 01948-061001	Application No. 09/778,013
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR 1.98(b))		Applicant Terry Strom, et al.	
		Filing Date February 6, 2001	Group Art Unit 1645

Other Documents (include Author, Title, Date, and Place of Publication)

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	AR	Almond, et al. *Risk Factors for Chronic Rejection in Renal Allograft Recipients.* Transplantation 55(4):752-757 (Apr. 1993).
	AS	Alpert, et al. *The Relationahip of Granzyme A and Perforin Expression to Cardiac Allograft Rejection and Dysfunction.* Transplantation 60(12):1478-1485 (Dec. 1995).
	AT	Amersi, et al. *Upregulation of heme oxygenase-1 protects genetically fat Zucker rat livers from ischemia/reperfusion injury.* J. Clin. Invest. 104:1631-1639 (1999).
	AU	Atkinson, et al. *Cytotoxic T Lymphocyte-assisted Suicide.* J. Biological Chemistry 273(33):21261-21266 (1998).
	AV	Bach, et al. *Accomodation of vascularized xenografts: expression of "protective genes" by donor endothelial cells in host Th2 cytokine environment.* Nature Medicine 3(2):196-204 (Feb. 1997).
	AW	Bach, et al. *Protective genes expressed in endothelial cells: a regulatory response to injury.* Immunology Today, Oct. 1997.
	AX	Badrichani, et al. *Bcl-2 and Bcl-X_L serve an anti-inflammatory function in endothelial cells through inhibition of NF-κB.* J. Clin. Invest. 103(4):543-553 (1999).
	AY	Beckingham, et al. *Analysis of factors associated with complications following renal transplant needle core biopsy.* British Journal of Urology 73:13-15 (1994).
	AZ	Benfield, et al. *Safety of kidney biopsy in pediatric transplantation.* Transplantation 67(4):544-547 (Feb. 1999).
	AAA	Berke. *Unlocking the secrets of CTL and NK cells.* Immunology Today 16(7):343-346 (1995).
	ABB	Boise, et al. *bcl-x, a bcl-2-Related Gene That Functions as a Dominant Regulator of Apoptotic Cell Death.* Cell 74:597-608 (Aug. 1993).
	ACC	Carraway, et al. *Expression of heme oxygenase-1 in the lung in chronic hypoxia.*
	ADD	Clement, et al. *Perforin and Granzyme B Expression is Associated with Severe Acute Rejection.* Transplantation 57(3):322-326 (Feb. 1994).
	AEE	Choi, et al. *Heme Oxygenase-1: Function, Regulation, and Implication of a Novel Stress-inducible Protein in Oxidant-inducing Lung Injury.* Amer. J. of Respiratory Cell and Molecular Biology 15:9-19 (1996).
	AFF	Colvin, et al. *Evaluation of Pathology Criteria for Acute Renal Allograft Rejection: Reproducibility, Sensitivity, and Clinical Correlation.* J. Am. Soc. Nephrol. 8:1930-1941 (1997).
	AGG	Cooper, et al. *A20 Blocks Endothelial Cell Activation through a NF-κB-dependent Mechanism.* Journal of Biological Chemistry 271(30):18068-18073 (1996).
	AHH	Cooper, et al. *A20 Expression Inhibits Endothelial Cell Activation.* Transplantation Proceedings, Barcelona, Aug. 1996.
	AII	DeBruyne, et al. *Gene Transfer of Immunomodulatory Peptides Correlates with Heme Oxygenase-1 Induction and Enhanced Allograft Survival.* Transplantation 69(1):120-128 (2000).
	AJJ	Dong, et al. *Heme Oxygenase-1 in Tissue Pathology.* American Journal of Pathology 156(5):1485-1488 (2000).
	AKK	Ferran, et al. *A20 Inhibits NF-κB Activation in Endothelial Cells Without Sensitizing to Tumor Necrosis Factor-Mediated Apoptosis.* Blood 91(7):2249-2258 (1998).
	ALL	Gaber, et al. *Correlation of histology to clinical rejection reversal: A Thymoglobulin Multicenter Trial report.* Kidney International 55:2415-2422 (1999).

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	AMM	Gulanikar, et al. *The incidence and impact of early rejection episodes on graft outcome in recipients of first cadaver kidney transplants.* Transplantation 53(2):323-328 (1992).
	ANN	Hancock, et al. *Antibody-induced transplant arteriosclerosis is prevented by graft expression of anti-oxidant and anti-apoptotic genes.* Nature Medicine 4(12):1392-1396 (1998).
	AOO	Hariharan, et al. *Improved graft survival after renal transplantation in the United States, 1988 to 1996.* The New England Journal of Medicine 342(9):605-612 (2000).
	APP	Henkart. *Lymphocyte-Mediated Cytotoxicity: Two Pathways and Multiple Effector Molecules.* Immunity 1:343-346 (1994).
	AQQ	Heusel, et al. *Cytotoxic Lymphocytes Require Granzyme B for the Rapid Induction of DNA Fragmentation and Apoptosis of Allogenic Target Cells.* Cell 76:977-987 (1994).
	ARR	Huraib, et al. *Percutaneous Needle Biopsy of the Transplanted Kidney: Technique and Complications.* American Journal of Kidney Diseases 14(1):13-17 (1989).
	ASS	Kagi, et al. *Cytotoxicity mediated by T cells and natural killer cells is greatly impaired in perforin-deficient mice.* Nature 369:31-37 (1994).
	ATT	Kagi, et al. *Molecular mechanisms of lymphocyte-mediated cytotoxicity and their role in immunological protection and pathogenesis in vivo.* Annu. Rev. Immunol. 14:207-232 (1996).
	AUU	Krams, et al. *Expression of the cytotoxic T cell mediator granzyme B during liver allograft rejection.* Transplant Immunology 3:162-166 (1995).
	AVV	Lee, et al. *Overexpression of heme oxygenase-1 in human pulmonary epithelial cells results in cell growth arrest and increased resistance to hyperoxia.* Proc. Natl. Acad. Sci. USA 93:10393-10398 (1996).
	AWW	Legros-Maida, et al. *Granzyme B and perforin can be used as predictive markers of acute rejection in heart transplantation.* Eur. J. Immunol. 24:229-233 (1994).
	AXX	Lin, et al. *Accomodated Xenografts Survive in the Presence of Anti-donor Antibodies and Complement That Precipitate Rejection of Naïve Xenografts.* Journal of Immunology 163:2850-2857 (1999).
	AYY	Lindholm, et al. *The impact of acute rejection episodes on long-term graft function and outcome in 1347 primary renal transplants treated by 3 cyclosporine regimens.* Transplantation 56(2):307-315 (1993).
	AZZ	Lipman, et al. *Heightened Intragraft CTL Gene Expression in Acutely Rejecting Renal Allografts.* Journal of Immunology 152:5120-5127 (1994).
	AAAA	Littell, et al. *SAS® System for Mixed Models.* SAS Institute, Inc. (1996).
	ABBB	Liu, et al. *Perforin: structure and function.* Immunology Today 16(4):194-201 (1995).
	ACCC	Maines. *The Heme Oxygenase System: A regulator of second messenger gases.* Annu. Rev. Pharmaco. Toxicol. 37:517-554 (1997).
	ADDD	Nath, et al. *Induction of Heme Oxygenase is a Rapid, Protective Response in Rhabdomyolysis in the Rat.* J. Clin. Invest. 90:267-270 (1992).
	AEEE	Nath, et al. *The Indispensability of Heme Oxygenase-1 in Protecting Against Acute Heme Protein-Induced Toxicity in Vivo.* American Journal of Pathology 156(5):1527-1535 (2000).
	AFFF	Nicholson, et al. *A prospective randomized trial of three different sizes of core-cutting needle for renal transplant biopsy.* Kidney International 58:390-395 (2000).

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	AGGG	Ohta, et al. *Tubular Injury as a Cardinal Pathologic Feature in Human Heme Oxygenase-1 Deficiency.* American Journal of Kidney Diseases 35(5):863-870 (2000).
	AHHH	Opipari, et al. *The A20 cDNA Induced by Tumor Necrosis Factor α Encodes a Novel Type of Zinc Finger Protein.* Journal of Biological Chemistry 265(25):14705-14708 (1990).
	AIII	Opipari, et al. *The A20 Zinc Finger Protein Protects Cells from Tumor Necrosis Factor Cytotoxicity.* Journal of Biological Chemistry 267(18):12424-12427 (1992).
	AJJJ	Otterbein, et al. *Carbon monoxide has anti-inflammatory effects involving the mitogen-activated protein kinase pathway.* Nature Medicine 6(4):422-428 (2000).
	AKKK	Racusen, et al. *The Banff 97 working classification of renal allograft pathology.* Kidney International 55:713-723 (1999).
	ALLL	Rush, et al. *Histological findings in early routine biopsies of stable renal allograft recipients.* Transplantation 57(2):208-211 (1994).
	AMMM	Rush, et al. *Beneficial Effects of Treatment of Early Subclinical Rejection: A Randomized Study.* J. Amer. Soc. Nephrol. 9:2129-2134 (1998).
	ANNN	Sarma, et al. *Activation of the B-cell Surface Receptor CD40 Induces A20, a Novel Zinc Finger Protein That Inhibits Apoptosis.* Journal of Biological Chemistry 270(21):12343-12346 (1995).
	AOOO	Schulz, et al. *Acute rejection of vascular heart allografts by perforin-deficient mice.* Eur. J. Immunol. 25:474-480 (1995).
	APPP	Sharma, et al. *Molecular Executors of Cell Death-Differential Intrarenal Expression of Fas Ligand, Fas, Granzyme B, and Perforin during acute and/or chronic rejection of human renal allografts.* Transplantation 62(12):1860-1866 (1996).
	AQQQ	Shoskes, et al. *Deleterious effects of delayed graft function in cadaveric renal transplant recipients independent of acute rejection.* Transplantation 66(12):1697-1701 (1998).
	ARRR	Smyth. *Dual mechanisms of lymphocyte-mediated cytotoxicity serve to control and deliver the immune response.* Bioessays 17(10):891-898 (1995).
	ASSS	Smyth, et al. *Granzymes: exogenous proteinases that induce target cell apoptosis.* Immunology Today 16(4):202-206 (1995).
	ATTT	Soares, et al. *Expression of heme oxygenase-1 case determine cardiac xenograft survival.* Nature Medicine 4(9):1073-1077 (1998).
	AUUU	Sorof, et al. *Histopathological concordance of paired renal allograft biopsy cores.* Transplantation 60(11):1215-1219 (1995).
	AVVV	Strehlau, et al. *Quantitative detection of immune activation transcripts as a diagnostic tool in kidney transplantation.* Proc. Natl. Acad. Sci. USA 94:695-700 (1997).
	AWWW	Strom, et al. *Identity and cytotoxic capacity of cells infiltrating renal allografts.* New England Journal of Medicine 292(24):1257-1263 (1975).
	AXXX	Suthanthiran, et al. *Excellent outcome with a calcium channel blocker-supplemented immunosuppressive regimen in cadaveric rental transplantation.* Transplantation 55(5):1008-1013 (1993).
	AYYY	Suthanthiran, et al. *Renal Transplantation.* New England Journal of Medicine 331(6):365-376 (1994).
	AZZZ	Tewari, et al. *Lymphoid expression and regulation of A20, an inhibitor of programmed cell death.* Journal of Immunology 154:1699-1706 (1995).

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	AAAAA	Vogt, et al. *Glomerular Inflammation Induces Resistance to Tubular Injury in the Rat.* J. Clin. Invest. 98:2139-2145 (1996).
	ABBBB	Willis, et al. *Heme oxygenase: a novel target for the modulation of the inflammatory response.* Nature Medicine 2(1):87-90 (1996).
	ACCCC	Yachie, et al. *Oxidative stress causes enhanced endothelial cell injury in human heme oxygenase-1 deficiency.* Journal of Clinical Investigation 103(1):129-135 (1999).
	ADDDD	Yoshida, et al. *Human heme oxygenase cDNA and induction of its mRNA by hemin* Eur. J. Biochem. 171:457-461 (1988).

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